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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/486,392	06/15/00	KIM	H 012679-066

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EXAMINER

FOLEY, S

ART UNIT	PAPER NUMBER
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1648

9

DATE MAILED: 03/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/486,392

Applicant(s)

KIM ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 9, and 10 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-7, 9, and 10 are pending in the application.

#### ***Response to Arguments***

Applicant's arguments filed 1/31/01 in paper no. 8 have been fully considered but they are not persuasive.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Huiying et al.

Applicant argues that the attenuated strain Japanese encephalitis virus used by Huiying et al. is a completely different strain that is claimed and therefore does not anticipate the claimed invention.

Claims 1, 4, 6, 7, and 10 do not recite a specific Japanese encephalitis virus strain. Claims 1, 4, 6, 7, and 10 are drawn to an attenuated Japanese encephalitis virus vaccine adapted to Vero cells that is untreated by an inactivating agent in a pharmaceutically acceptable carrier. Therefore, the Japanese encephalitis virus, P<sub>3</sub>, that has been adapted in Vero cells that Huiying et al. teaches, anticipates claims 1, 4, 6, 7, and 10. Huiying et al. teaches a method of virus propagation is proposed for vaccine production to avoid the possible contamination of extraneous agents compared with using the virus from the mouse brain, see the abstract. Claims

Art Unit: 1648

4, 6, 7, and 10 require only virus and carrier, the reference virus composition meets these claim limitations. In addition, a vaccine by definition is administered to an organism for the prevention and/or treatment of an infectious disease and therefore, by definition is contained in a pharmaceutically acceptable carrier.

In addition, Applicants argue that the virus titer produced by Huiying et al. is significantly less than the claimed titer and that the method disclosed by Huiying et al. is not suitable for the production of vaccine on an industrial scale.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., virus titer and industrial vaccine production) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huiying et al. as applied to claims 1, 4, 6, 7, and 10 above, and further in view of Barrett.

Applicant argues that Barrett fails to teach an attenuated JE virus adapted to VERO cells. Applicant also argues that Barrett does not teach a JE virus produced at a high titer or the LD<sub>50</sub> in mice. Again, these claim limitations cannot be found in claims 5 or 9. Claims 5 and 9 are drawn to an inactivated Japanese encephalitis virus vaccine that has been inactivated by an inactivating agent.

Art Unit: 1648

Barret et al. teaches the Nakayama formalin-inactivated Japanese encephalitis vaccine that have been commercially available since 1973 that was grown in mouse brain. Another formalin-inactivated Japanese encephalitis virus vaccine commercially available since 1968 is the Peking 3 grown in primary hamster kidney cells. The immunity of these vaccines are short-lived and subsequent booster shots are necessary, see "Inactivated vaccines" and "Immunization regimen and seroconversion" on pages 27-28.

One of ordinary skill in the art at the time the invention was made would have been motivated to inactivate an attenuated Japanese encephalitis virus in Vero cells taught by Huiying et al. to protect people who are immunocompetent. From the teaching of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because of inherent low virulence of the inactivated vaccines taught by Barret above that require extensive boosters of the vaccine to maintain an immune response. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references.

***Allowable Subject Matter***

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2 and 3 are drawn to an attenuated Japanese Encephalitis virus, CJ50003, which has a multiplicity of more than  $1 \times 10^7$  PFU/ml in Vero cells and  $LD_{50}$ /pfu for mice is less than 0.000001.

The claims are free of the art. The closest prior art is recited above. None of the references teach the specific strain recited in the claim, or any attenuated Japanese Encephalitis virus with those specific characteristics.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Application/Control Number: 09/486,392

Page 6

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley  
March 5, 2001

*Mary Mosher*  
**MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800**

*1600*